

## I. REMARKS

In the Office Action mailed June 26, 2008 the Examiner objected to claims 61, 64, 77-79 and the Examiner rejected claims 61-64, 67-72, and 76-79 as being obvious. Applicants have cancelled claims 61-80 without prejudice to pursue them in a continuing application and Applicant is presenting new claims 81-96. Support for the new claims under 35 U.S.C. § 112 can be found in the specification in Paragraphs 0043, 0052, 0059, 0082, 0090, 0092, and Figures 11c and 12c. Applicants believe that the new set of claims is patentable. The foregoing amendments are taken in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicant would otherwise be entitled in view of the prior art.

## II. CLAIM OBJECTIONS

Applicants have cancelled claims 61, 64, and 77-79; therefore, the objection has been rendered moot.

## III. CLAIM REJECTIONS – 35 USC § 103

The Office Action rejected claims 61-64, 67-72, and 76-79, and states that "Hoyns fails to disclose the first ends of the first and second arc segments project in a direction away from the second ends of the first and second arc segments." The Office Action then goes on to state that it would have been obvious to one having ordinary skill in the art to orient the ends as claimed. Next, the Office Action states that it is the Applicant's burden to show why a clip with ends projecting away from each other **"provides an advantage, is used for a particular purpose, or solves a stated problem."** The rejection concludes by stating that **"it appears the prior art clip having first ends projecting towards the second ends would perform equally well."** The rejection is incomprehensible especially in view of the teachings at Page 4, Paragraph 0056 and 0059, and Page 6, Paragraph 0080, which state the advantages of the Selis clip. If the Examiner is to maintain the rejection on this basis the Examiner must clarify the rejection and support the arguments with facts, supported by evidence, and case law.<sup>1</sup> Moreover, the Examiner is taking a conflicting position; previously the Examiner stated that the Selis Application was

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<sup>1</sup> As mentioned previously it is not understood whether the Examiner is attacking the species elected as compared with the other disclosed species. If so, then this is believed to be erroneous and unsupported by law.

patentable over Hoyns and now the Examiner is rejecting the Selis Application based on Hoyns.<sup>2</sup>

a) Incorrect Fact Findings and Lack of Evidence

The current rejection is not based on facts or evidence. A properly performed fact finding would show that the rejections are improper and should not be maintained. The facts as set forth below show that a rejection using Hoyns cannot be maintained.<sup>3</sup>

The Office Action arrives at this faulty fact finding that is contrary to the evidence including the passages in the specification that say, "One benefit of the present invention is that the clip deployment can be accomplished with or without a vacuum assist," and "The design of the clips 120 helps to avoid the possibility of migration." The Office Action suggests that Hoyns does not teach a clip with ends projecting away from each other; Hoyns does not teach this because the Hoyns clip relies on springing and clamping to prevent migration. The Office Action fails to recognize that Hoyns teaches away from having a clip with the ends projecting away from each other. Support is found in Hoyns Column 1, lines 54-57 where Hoyns states, "Thus, there is a need for a marker which automatically mechanically attaches to the target tissues upon being deployed, without the need for intervention by the surgeon." And in column 2, lines 42-44 where Hoyns states, "Upon the marker exiting the forward end of the needle the barbs spring outward, anchoring the marker to the tissue."

Hoyns "solved" the problem of migration by using a spring action and a clamping action. If the Hoyns clip was modified as suggested by the Office Action there would be

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<sup>2</sup> Currently this case is being rejected by Hoyns et al. (6,766,186). In a previous Office Action, dated March 06, 2007, Hoyns was cited as a reference and the reference was discussed at length with both the Examiner and the Examiner's Supervisor, Anh Tuan Nguyen, during an in-person interview. After this in-person interview the case was allowed, over the Hoyns reference stating:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hoyns et al. (Patent No. 6,766,186 B1) discloses a post biopsy tissue marker (Figure 14). It is noted that the first ends (66) of the first (61) and second (62) arc segments project in a direction towards the second ends (66) of the first (61) and second (62) arc segments, therefore, Hoynes et al. does not read on claim 61. (emphasis added)

The issue fee was subsequently paid. Due to the withdrawal of issue and a Final Office Action based on the Hoyns reference, the Applicant is being unduly burdened with additional expenses. The Applicant is a sole inventor with finite resources.

<sup>3</sup> The Office Action states that the burden of proof is on the Applicant to show an advantage, a use for a particular purpose, or solving a stated problem. The Office Action incorrectly states that the Applicant bears this burden. Support for this can be found in the MPEP § 2142 where the MPEP states, "The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness." The Office Action has neither pointed to any facts that show why the clip in the Selis Application is obvious nor has the Office Action put forth any evidence supporting an obviousness rejection. The Office Action merely states conclusions that are not supported by the art referenced. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007) said, "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR, 82 USPQ2d at 1396 (quoting *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)). Moreover, the MPEP § 2142 states, "If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness." (emphasis added). Therefore, the Applicant is not required to state why the clip has an advantage, is used for a particular purpose, or solves a stated problem.

no springing action and no clamping action. Therefore, the Hoyns clip would no longer perform the functions it teaches to prevent migration. The Office Action failed to address the fact that the Selis Application does not teach or rely on clamping or springing. This is an importation difference between the Selis Application and Hoyns—that was never addressed in the office action.

As set forth in MPEP 2143.01 THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE. On the present facts, the modifications suggested by the Examiner to Hoyns, for example, would render the resulting structures unsuitable for their intended purpose. For example, the Examiner has failed to show how the Hoyns clip can be modified to achieve the claimed process without eliminating the critical element in Hoyns of the springing and clamping action. See *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). See also *In re Fritch* (CA FC 1992) 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992)("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification").

The Office Action also fails to make any findings that there was any motivation to modify Hoyns or that the modifications the Office Action asserts was merely one of a finite number of predictable solutions. There are infinite ways Hoyns might have been modified without arriving at the claimed invention. For example, Hoyns could be modified by: having an A-symmetrical geometry, using dissimilar materials for the barbs, varying the material properties along the device, varying the dimensions, varying the orientation of the barbs in three-dimensional space, and so on and so forth. The Office Action ignores this requirement under *KSR*, and has not met its burden to establish a prima facie obviousness.

b) Improper Application of *KSR*

Applicant believes that the Office Action did not set forth an appropriate analysis to satisfy the Supreme Court's requirements from *KSR International co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007). The Office has the burden to explicitly analyze:

. . . interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In*

*re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")....

Applicant believes the rejections to date are mere conclusory statements absent any "articulated reasoning with some rational underpinning to support the legal conclusions of obviousness." The Office Action fails to point out with any particularity where Hoyns teaches a clip that does not spring or claim. The Office Action further fails to state where Hoyns teaches a clip as shown in the Selis Application. The Office Action states that it would have been obvious to create the clip in the Selis Application; however, the Hoyns clip and the practice in the industry teach away from creating a clip as shown in the Selis Application. Therefore, a proper rejection under *KSR* was not made.

#### IV. CONCLUSIONS

In view of Applicant's remarks, the Examiner's previously presented rejections are believed to be rendered moot. Accordingly, Applicant submits that the present application is in condition for allowance and requests that the Examiner pass the case to issue at the earliest convenience. Should the Examiner have any question or wish to further discuss this application, Applicant requests that the Examiner contact the undersigned at (248) 292-2920.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge Deposit Account No. 50-1097 for any fee which may be due.

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